

November 26, 2013



U.S. Department  
of Transportation

East Building, PHH-30  
1200 New Jersey Avenue S.E.  
Washington, D.C. 20590

**Pipeline and Hazardous  
Materials Safety Administration**

DOT-SP 14523  
(THIRD REVISION)

**EXPIRATION DATE: August 31, 2017**

(FOR RENEWAL, SEE 49 CFR § 107.109)

1. GRANTEE: Pacific Bio-Material Management, Inc.  
Fresno, CA
2. PURPOSE AND LIMITATION:
  - a. This special permit authorizes the transportation in commerce of certain infectious substances in special packagings (freezers). This special permit provides no relief from the Hazardous Materials Regulations (HMR) other than as specifically stated herein. The most recent revision supersedes all previous revisions.
  - b. The safety analyses performed in the development of this special permit only considered the hazards and risks associated with the transportation in commerce.
  - c. No party status will be granted to this special permit.
3. REGULATORY SYSTEM AFFECTED: 49 CFR Parts 106, 107 and 171-180.
4. REGULATIONS FROM WHICH EXEMPTED: 49 CFR §§ 173.196(a) and 173.199(a) in that alternate packagings are authorized as specified herein; and §§ 178.603 and 178.609(d) in that the drop tests are waived.
5. BASIS: This special permit is based on the application of Pacific Bio-Material Management, Inc. dated August 28, 2013, submitted in accordance with § 107.109.

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6. HAZARDOUS MATERIALS (49 CFR § 172.101):

Hazardous Materials Description			
Proper Shipping Name	Hazard Class/ Division	Identification Number	Packing Group
Infectious substances, affecting animals <i>only</i>	6.2	UN2900	N/A
Infectious substances, affecting humans	6.2	UN2814	N/A
Biological substance, Category B	6.2	UN3373	N/A

7. SAFETY CONTROL MEASURES:a. PACKAGING -

(1) Watertight vials (primary receptacles) ranging in size from 2 ml to 10 ml must be secured in individual cells of stainless steel boxes.

(2) Closed stainless steel boxes must be packed in a plastic bag which must be heat-sealed and watertight (secondary packaging). The boxes must be secured in stainless steel racks. A rack holds from 10 to 13 boxes.

(3) The freezer serves as outer packaging which is a large capacity, commercial grade, double-walled, stainless, liquid-nitrogen cooled freezer (a MVE Model 1840HE freezer or a Taylor Wharton Model LABS 80K freezer). Racks must be secured in sectors of the freezer to prevent tipping or shifting of the racks. Sufficient absorbent material must be placed in the freezer to absorb the entire contents of all primary receptacles in case of breakage or leakage. The freezer may contain approximately 10,000 (8 mL)- 30,000 (2 mL)vials depending upon the size of the vial with a maximum total content not to exceed 100 L of the substances in the vials, and liquid nitrogen to keep the infectious substances at the operating temperature for at least twice the estimated travel distance. A

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back-up freezer system and liquid nitrogen sufficient to keep the infectious substances within the operating temperature range for at least twice the estimated travel time must be carried on the transport vehicle.

b. OPERATIONAL CONTROLS -

(1) A specialized dedicated transport vehicle must be used to transport packages containing infectious substances.

(2) Packages must be prepared, transported, and unpacked by trained employees of Pacific Bio-Material Management, Inc.

(3) Not more than one transport vehicle may be operated at all times.

(4) Not more than eight (8) freezers may be in a transport vehicle.

(5) All freezers must be secured against movement in the transport vehicle, and strapped around the doors to keep them closed.

(6) An itemized list of contents must be secured to the outside of each freezer.

(7) Emergency refrigeration and response equipment and procedures must be in place and operational to address loss of refrigeration, delay in transportation or release of an infectious substance.

(8) The Department of Transportation must be notified five (5) business days prior to each move indicating the date of the move, the amounts to be moved, the origin and destination of the move, the routes of transport, any arrangements with appropriate governmental agencies, and any other safety measures.

8. SPECIAL PROVISIONS:

a. A current copy of this special permit must be maintained at each facility where the package is offered or reoffered for transportation.

b. Each outer packaging (freezer) must be marked "DOT-SP 14523" in accordance with § 172.302(c).

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9. MODES OF TRANSPORTATION AUTHORIZED: Motor Vehicle.
10. MODAL REQUIREMENTS: A current copy of this special permit must be carried aboard each motor vehicle used to transport packages covered by this special permit.
11. COMPLIANCE: Failure by a person to comply with any of the following may result in suspension or revocation of this special permit and penalties prescribed by the Federal hazardous materials transportation law, 49 U.S.C. 5101 et seq:
  - o All terms and conditions prescribed in this special permit and the Hazardous Materials Regulations, 49 CFR Parts 171-180.
  - o Persons operating under the terms of this special permit must comply with the security plan requirement in Subpart I of Part 172 of the HMR, when applicable.
  - o Registration required by § 107.601 et seq., when applicable.

Each "Hazmat employee", as defined in § 171.8, who performs a function subject to this special permit must receive training on the requirements and conditions of this special permit in addition to the training required by §§ 172.700 through 172.704.

No person may use or apply this special permit, including display of its number, when this special permit has expired or is otherwise no longer in effect.

Under Title VII of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA-LU) - "The Hazardous Materials Safety and Security Reauthorization Act of 2005" (Pub. L. 109-59), 119 Stat. 1144 (August 10, 2005), amended the Federal hazardous materials transportation law by changing the term "exemption" to "special permit" and authorizes a special permit to be granted up to two years for new special permits and up to four years for renewals.

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12. REPORTING REQUIREMENTS: Shipments or operations conducted under this special permit are subject to the Hazardous Materials Incident Reporting requirements specified in 49 CFR §§ 171.15 Immediate notice of certain hazardous materials incidents, and 171.16 Detailed hazardous materials incident reports. In addition, the grantee(s) of this special permit must notify the Associate Administrator for Hazardous Materials Safety, in writing, of any incident involving a package, shipment or operation conducted under terms of this special permit.

Issued in Washington, D.C.:



for Dr. Magdy El-Sibaie  
Associate Administrator for Hazardous Materials Safety

Address all inquiries to: Associate Administrator for Hazardous Materials Safety, Pipeline and Hazardous Material Safety Administration, U.S. Department of Transportation, East Building PHH-30, 1200 New Jersey Avenue, Southeast, Washington, D.C. 20590.

Copies of this special permit may be obtained by accessing the Hazardous Materials Safety Homepage at [http://hazmat.dot.gov/sp\\_app/special\\_permits/spec\\_perm\\_index.htm](http://hazmat.dot.gov/sp_app/special_permits/spec_perm_index.htm) Photo reproductions and legible reductions of this special permit are permitted. Any alteration of this special permit is prohibited.

PO: STH/TG